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10/589,658	08/16/2006	Kazuhiko Katou	294828US0PCT	9975
22850 7590 01/06/2011 OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P. 1940 DUKE STREET ALEXANDRIA, VA 22314				
EXAMINER WELTER, RACHAEL E				
ART UNIT		PAPER NUMBER		
1611				
NOTIFICATION DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/589,658

Applicant(s)

KATOU ET AL.

Examiner

RACHAEL E. WELTER

Art Unit

1611

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Status

Claims 1-13 are pending. Claims 7-13 are newly added.

Acknowledgements

Receipt of the amendment and remarks/arguments filed on 8/26/10 is acknowledged.

New Rejection

The following rejections constitute new grounds for rejection necessitated by amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-6, 8-9, and 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The amendments to claims 1 and 3 have introduced new matter into the claims. Claims 1 and 3 recite an equation which is satisfied prior to the adding, combining, or

mixing the toothpaste composition. Applicant points out support for this equation in paragraph [0016] of the specification. Although applicant has support for the specific equation, the specification seems to have no explicit support for the limitation wherein the equation is satisfied prior to the adding, combining, or mixing of the composition. The equation in the specification seems to be referring to the toothpaste composition obtained after adding, combining or mixing and not prior to adding, combining, or mixing the toothpaste composition. As such, in order to have adequate support for the amended claims, applicant must prove that the specification explicitly states and/or exemplifies that the instant equation is satisfied prior to the adding, combining, or mixing of the composition.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-6, 8-9, and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 3 recite an equation which is satisfied prior to the adding, combining, or mixing the toothpaste composition. However, it is unclear how the equation, which relates to how much erythritol is dissolved or undissolved in the water, could be satisfied prior to the mixing of water and erythritol. Does applicant mean that the equation is satisfied after components (A), (B), and (C1) are combined and mixed? If so, it is not clear how the equation further limits the claims since the equation seems

to be based on the amounts of the components already recited in the claim.

Furthermore, if the equation is based on such amounts already recited in the claims, it is not satisfied for the entire ranges of water and erythritol recited. For instance, substituting 30 wt.% of erythritol and 30 wt.% water into the equation does not make the left side of the equation less than or equal to the right side of the equation. As such, applicant's clarification is respectfully requested.

In rejecting the claims over prior art, the examiner will interpret the claims as just containing a toothpaste composition comprising the recited amounts.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leusch et al (WO 00/56276) in view of De Sadeleer et al (US Patent No. 5,973,212).

Claims 7-13 are newly appended to this rejection.

Leusch et al teach oral care compositions including tooth pastes, mouth rinses, mouth sprays, chewing gums, and lozenges (abstract). In Example VI of Leusch et al, a composition comprising 10 wt.% erythritol, 0.31 wt.% xanthan gum, 0.45 wt.% carboxymethyl cellulose, and 23.56 wt.% water is taught (pg. 19). Leusch et al further teach that erythritol and other non-cariogenic carbohydrates can be comprised in the composition in an amount of 1-65 wt.% (pg. 3, lines 1-2). Besides sodium carboxymethyl cellulose and xanthan gum, Leusch et al teach additional thickening agents such as carrageenan (pg. 9, lines 1-6). Such thickening agents can be present in an amount of 0.1-15 wt.% and preferably 2-10 wt.% (pg. 9, lines 18-20). Additionally, Leusch et al teach that coolants can be added to its compositions (pg. 10, lines 5-8).

Although the particle size of erythritol in Leusch et al may be the same as claimed, Leusch et al do not explicitly teach erythritol having an average particle size of 200 um or less.

De Sadeleer et al teach erythritol compositions which are useful in tableting, chewing gum, chocolate, crystallized tablets, and fondants (column 2, lines 1-2). The erythritol preferably has a particle size of 10-250 microns (column 2, lines 17-19). According to De Sadeleer et al, the perception of cooling effect by the mouth is dependent upon the particle size of the erythritol crystals and for maximum effect it is desirable to use small but integral and non-fragmented crystals in its applications (column 2, lines 56-63).

Therefore, it would have been obvious to an artisan of ordinary skill at the time the invention was made to incorporate the instant particle size of erythritol in the compositions of Leusch et al. One would have been motivated with a reasonable expectation of success since De Sadeleer et al teach that such particle sizes are preferable in creating a cooling effect and Leusch desires the optional use of coolants in its compositions. Thus, if one desired to provide an oral care composition with a cooling effect, one would be motivated to add erythritol with the instant particle size.

Regarding the instant limitation of claim 6, wherein the composition has a viscosity at 25°C from 1500-5000 dPas, it is the position of the examiner that this would be an obvious expected property of the composition taught by Leusch et al and De Sadeleer et al because the prior art suggests the same components as the instant application including the erythritol, water, and binders. According to MPEP 2112.02, products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or

claims are necessarily present as *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Burden shifts to applicant to show unexpected results by declaration or otherwise as *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980). Furthermore, as evidenced by the instant specification, a binder content exceeding 3 wt.% has an unduly high viscosity (see paragraph 0014). Since Leusch et al suggest the instant binder amount; it is assumed that the composition of Leusch et al exhibits the instant viscosity.

Furthermore, regarding the amounts of the recited components in the instant claims, it is noted that the prior art cited above teaches amounts that either encompass or overlap with the amounts recited in the instant claims. Therefore, it would have been obvious to an artisan of ordinary skill at the time the invention was made to manipulate and optimize the amounts of the prior art because methods of determining appropriate component percentages are well-known in the art, and one of skill in the art would have arrived at the appropriate percentages via routine experimentation. Manipulation of relative amounts of formulation components do not support the patentability of subject matter encompassed by the prior art, unless there is evidence indicating unexpected results.

Regarding the new limitations of 13-14, wherein the erythritol is obtained by grinding crystalline erythritol, it is noted that this limitation is a product-by-process limitation. As a result, a determination of patentability is only based on the product itself. Applicant is directed to MPEP 2113, which states that "If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the

claim is unpatentable even though the prior product was made by a different process."

In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Response to Arguments

Applicant's arguments filed 8/26/10 have been fully considered but they are not persuasive.

Applicant argues that they have amended their independent claims to recite an equation representing how much erythritol component is dissolved/undissolved in water. Applicant notes that a lack of complete dissolution of the erythritol in the composition creates an improved cooling sensation that can be experienced by a person during use. Applicant submits that Leusch is silent with respect to the dissolution of erythritol and argues that Example VI of Leusch which contains 10 wt.% erythritol and 23.54 wt.% water would contain completely dissolved erythritol. Furthermore, applicant argues that Leusch does not teach a composition that achieves an enhanced cooling sensation in the mouth.

In response to applicant's arguments, the examiner first directs applicant's attention to the 112 rejections above. The examiner cannot determine if the equation is further limiting the amounts of (A), (B), and (C1) and thus will interpret the claims as just containing a toothpaste composition comprising the recited amounts. Although Leusch's Example VI is noted, the examiner points out that the instant rejection is made under obviousness and not anticipation. Therefore, the criteria for establishing a case of prima facie obviousness is not whether the prior art exemplifies all the claimed

limitations but whether the prior art suggests the claimed limitations. According to MPEP 2123, "Disclosed examples and preferred embodiments **do not constitute a teaching away form the broader disclosure** or nonpreferred embodiment." Leusch teaches a general range of erythritol of 1-65 wt.% (see pg. 3, lines 1-2). This is sufficient in establishing obviousness. Thus, because Leusch teaches amounts that overlap with the instant amounts, it would be implicit that Leusch's composition would have the dissolved/undissolved of erythritol in water that applicant desires.

Applicant further argues that De Sadeleer fails to make up for the deficiencies of Leusch. Furthermore, applicant argues that the claimed erythritol is prepared by grinding crystalline erythritol and not erythritol prepared by agglomeration with a binder as taught in De Sadeleer.

The examiner acknowledges applicant's arguments regarding DeSadeleer but notes that applicant's arguments regarding Leusch have been addressed above and are incorporated herein. It is noted that De Sadeleer was only cited for teaching erythritol's particle size and applicant has not argued this teaching. Although De Sadeleer may teach a different method of obtaining the erythritol, it is noted that this is a product-by process limitation. As a result, a determination of patentability is only based on the product itself.

As such, absent any persuasive arguments or unexpected results, it is the examiner's position that the rejection over Leusch in view of DeSadeleer should be maintained for the reasons stated above.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based

on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 6 of copending Application No. 11/512326. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The copending claims are drawn to a dentrifice composition comprising 15-60 wt.% erythritol having a particle size of less than 355 μ m, 10-40 wt.% water, and 0.6-3 wt.% binder. The binders can be selected from sodium carboxymethylcellulose, xanthan gum, and carrageenan.

Although the copending claims do not teach the same amounts of erythritol and water as the instant claims, the copending claims recite amounts that overlap with the instant claims.

However, it would have been obvious to an artisan ordinary skill at the time the invention was made manipulate and optimize the amount of water and erythritol in the composition of the copending claims. One would have been motivated to determine the optimal amount of each ingredient in order to best achieve the desired results. It should be noted that generally difference in concentrations do not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such a concentration is critical. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Regarding the instant limitation of claim 6, wherein the composition has a viscosity at 25°C from 1500-5000 dPas, it is the position of the examiner that this would be an obvious expected property of the composition recited by the copending claims because the claims recite the same components as the instant application including erythritol, water, and binders. According to MPEP 2112.02, products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present as *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Thus, burden shifts to applicant to show unexpected results by declaration or otherwise as *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Furthermore, as evidenced by the instant specification, a binder content exceeding 3 wt.% has an unduly high viscosity (see paragraph 0014). Since the copending claims recite the same binder amount as the instant claims, it is assumed that the composition of the copending claims exhibits the instant viscosity.

Regarding the new limitations of 13-14, wherein the erythritol is obtained by grinding crystalline erythritol, it is noted that this limitation is a product-by-process limitation. As a result, a determination of patentability is only based on the product itself. Applicant is directed to MPEP 2113, which states that "If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant requests this double patenting rejection be held in abeyance.

It is noted that a request to hold a rejection in abeyance is not a proper response to a rejection. Rather, a request to hold a matter in abeyance may only be made in response to an OBJECTION or REQUIREMENTS AS TO FORM (see MPEP 37 CFR 1.111(b) and 714.02). Thus, the double patenting rejection of record has been maintained as no action regarding this rejection has been taken by applicants at this time. The examiner also acknowledges that the present application has an earlier

effective filing date than the copending application and should be withdrawn if it remains the only rejection of record.

Conclusion

Claims 1-13 are rejected. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHAEL E. WELTER whose telephone number is (571) 270-5237. The examiner can normally be reached 7:30-5:00 Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached at 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

REW

/David J Blanchard/
Primary Examiner, Art Unit 1643